

Knowledge Acquisition Session Report Cancer Trials Support Unit – Westat, Inc.

Session Date: 7/25/01

Session Time: 2:00 – 3:15 p.m.

Session Topic: Cancer Trials Support Unit Common Data Element Needs

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Session Location: Westat Offices, Rockville, MD

Type of Session:

☒ Interview ☐ Task Analysis ☐ Scenario Analysis
☐ Concept Analysis ☐ Observation ☐ Structured Interview
☐ Other: _____

Documentation: KA Session Report

General Topic Area

Cancer Trials Support Unit Common Data Element Needs

Session Goals

- Document basic Clinical Trial Support Unit (CTSU) functions with respect to Common Data Elements
- Document CTSU problems using Common Data Elements

Summary

This report details the results of a Knowledge Acquisition session with Clinical Trial Support Unit (CTSU) personnel from Westat Corporation. The CTSU is tasked with streamlining data entry for clinical trials, and is therefore significantly interested in standardized, computer-base terms such as the Common Data Elements. Westat currently attempts to coordinate its data management systems with the CDE dictionary and with CDE compliance review results. Westat personnel described a number of concerns and problems with regard to their use of Common Data Elements. Some of these concerns relate to perceived inconsistencies in the CDE compliance review process. Other questions and concerns arise from perceived differences between Westat's data management system (Oracle Clinical) and the CDE standards based repository.

Background

The Cancer Trials Support Unit (CTSU) is a National Cancer Institute (NCI) pilot project designed to help physicians and patients participate in cancer clinical trials. On February 1, 2000 NCI awarded the CTSU contract jointly to three organizations:

- Westat Corporation
- Coalition of National Cancer Cooperative Groups
- Oracle Corporation's Health Informatics Consulting Practice

The CTSU was given three objectives:

1. To reduce the regulatory and administrative burdens on Clinical Trials Cooperative Groups sponsored by NCI by unifying and standardizing membership rosters and institutional review board approvals
2. To facilitate physician and patient access to NCI-sponsored clinical trials by developing an efficient enrollment procedure that will facilitate cross-Group accrual, and eventually permit non-Group members to enroll patients on NCI-sponsored trials
3. To streamline data entry and collection for clinical trials through the use of standard case report forms and reporting mechanisms

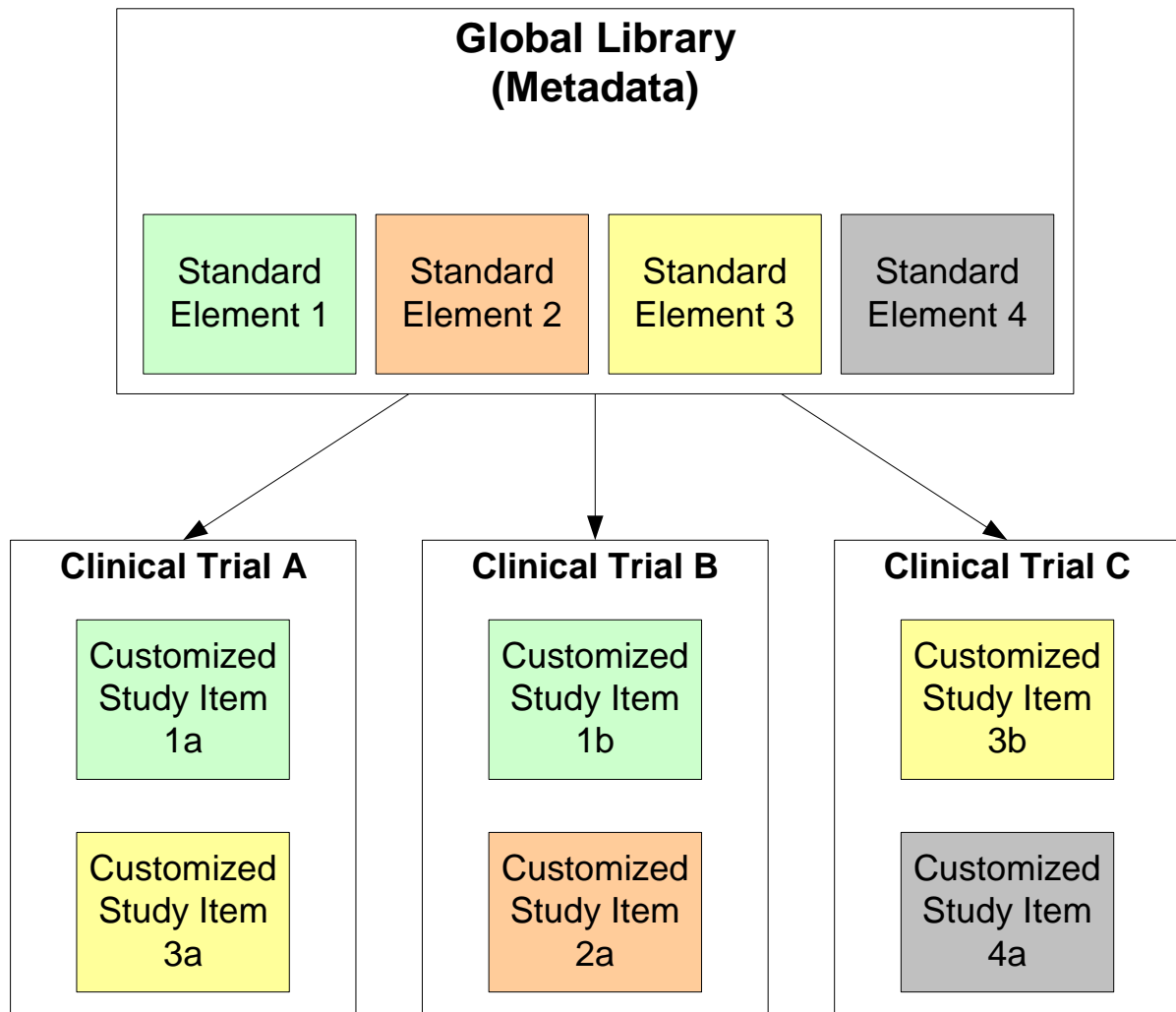
The Common Data Elements (CDE) effort centers on developing a standardized, computationally valid terminology that may be used for clinical trials. Such a terminology would be required for efficient computerized patient enrollment. The terminology would also be useful for creating standard case report forms (the forms used to capture all the data for each patient involved in a clinical trial). CTSU therefore has a significant interest in Common Data Elements.

CTSU Functions Related to CDEs

Cooperative group investigators may register their Phase III cancer treatment trials with CTSU. This allows other registered investigators to enroll patients on those trials. CTSU also supports remote data capture of case report form data for these clinical trials.

Westat maintains the data management system for CTSU to support case report form data management. For this purpose, Westat uses a non-customized Oracle Clinical system provided by Oracle Pharmaceutical Applications.

The Oracle Clinical system stores metadata in a Global Library, allowing users to define and characterize data elements. Users then draw from the Global Library to build Study Items that are specific to an individual clinical trial. Each Study Item may be customized for the clinical trial by changing labels, creating subsets, extending values, or altering prompts. Figure 1 shows the relationship between the Global Library and the Study Items.



Cooperative Groups submit cancer treatment clinical trial protocols and their associated case report forms to NCI's Cancer Therapy Evaluation Program (CTEP) for review and approval. That review includes an assessment of how well the case report forms comply with Common Data Element standards. CTEP sends spreadsheets containing the review results back to the submitting cooperative group, along with requests for changes to the case report forms. CTEP also sends the case report forms and review results to Westat for CTSU.

Westat evaluates the CDE review results and attempts to incorporate the CDE information into its Global Library. This is done in an effort to keep the CTSU data management system coordinated with the CDE standards. From that Global Library Westat then creates the Study Items needed for the clinical trial's case report forms. When Westat has questions about a common data element or a CDE review result, they use the web-based CDE dictionary to search for the relevant common data elements.

The Global Library does not support the use of synonyms. Therefore, a problem arises when the CDE compliance review requires an element name that is slightly different from one in the Global Library. In these cases Westat ignores the difference, adds a new term to cover the variation, or changes the Global Library term. However, a changed term may be changed back at a later time to support the needs of yet another protocol.

Westat/CTSU Concerns About CDEs

Westat personnel described a number of concerns and problems with regard to their use of Common Data Elements. Some of these concerns relate to perceived inconsistencies in the CDE compliance review process:

- The existing CDE dictionary has not been updated, so it is not reliable as a reference.
- CDE compliance review spreadsheets are sometimes incomplete.
- CDE compliance review spreadsheets sometimes contain unclear instructions.
- Rulings about CDE compliance seem inconsistent across clinical trials.
- CDE compliance reviews are unclear about what is final and what is a temporary approval.
- Common Data Elements have different statuses (provisional, proposed, common, etc.), but the status of any particular element may be unclear.
- Values and codes seem to be inconsistently applied in CDE compliance reviews.

Other questions and concerns arise from perceived differences between Westat's data management system (Oracle Clinical) and the CDE standards based repository:

- The Global Library does not support synonyms, but synonyms are used in CDEs.
- Many small variations in element names are acceptable in the CDEs, but cannot be easily handled in the Global Library.
- The Global Library does not support long CDE names, so they are ignored.
- Oracle Clinical has a 20 character limit for element names, and many short CDE names are longer than 20 characters.
- Westat uses a number of derived and calculated elements (e.g., conversion of temperature from Celsius to Fahrenheit), but they are unsure of the CDE standards based repository will allow these types of element definitions.
- Data elements in the standards based repository model do not seem to have statuses (approved, provisional, draft) associated with them.
- Can Question Name be added as an alias/synonym in the CDE standards based repository?